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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,277	02/05/1999	PAUL P. WORLEY	10496/005001	4724

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Lisa A Haile
Gray Cary Ware & Freidenrich LLP
Suite 1600
4365 Executive Drive
San Diego, CA 92121-2189

EXAMINER
CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/245,277	WORLEY ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11 and 14-61* is/are pending in the application.

4a) Of the above claim(s) *8-11 and 14-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 18 is acknowledged. However, since Applicant did not present any arguments to traverse the restriction, response to restriction requirements is considered as election without traverse. MPEP 818.03(a).

Claims 8-11 and 14-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 18.

Claims 44-61 are under examination in the instant office action.

Specification

2. The use of the trademarks has been noted in this application, see page 14, second paragraph, for example. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is advised to review the entire text of the instant specification for other possible use of trademarks.

3. Pages 44-51 include examples with citation of full-length sequences, which duplicate the information presented in the sequence listing. It is suggested that only references to sequences by

sequence identifiers be included in the text of the specification. If Applicant adopts this suggestion a substitute specification will be required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 44-61 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are

"useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated nucleic acid molecule and the protein encoded thereby of as yet undetermined function or biological significance. It is clear from the instant specification that the claimed novel nucleic acids relate to neuronal IEG (immediate early gene). "Such neuronal IEGs have been found to encode a wide variety of polypeptides including transcription factors, cytoskeletal polypeptides, growth factors, and metabolic enzymes as well as polypeptides involved in signal transduction" (page 1, lines 20-25 of the instant specification). More specifically, "nucleic acid clones for different neuronal IEGs were isolated and identified based on the ability of each IEG to rapidly increase expression upon seizure induction by a maximal electroconvulsive seizure (MECS) method" " (page 8, lines 4-6). Therefore, because the newly identified polypeptide of SEQ ID NO: 32 was expressed in response to seizure or ischemia, it was asserted that it "can influence neuronal activities involved in brain functions such as learning and memory" (page 8, lines 11-12). It was furthermore asserted that "the isolation and identification of IEG nucleic acid not only provides research scientists with information about neuronal activity and gene regulation but also provides methods and materials that can be used to manipulate brain function" (page 8, lines 12-14).

In the absence of knowledge of the biological significance of this specific nucleic acid and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. The fact that expression of polynucleotide of SEQ ID NO: 31, which is also identified as clone L119 (page 78-80), is upregulated in response to certain stimuli does not make an encoded polypeptide of SEQ ID NO: 32 immediately associated with learning or memory, as asserted in the instant specification. The instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that SEQ ID NO: 32 is involved in any specific identified "brain function". Therefore, one of ordinary skill in the art would not have reasonable basis for concluding that "[a]n animal (e.g., human) having a deficiency in a neuron's IEG responsiveness to a stimulus (e.g., a stimulus that influences learning or memory) can be treated using the methods and materials described [in the instant specification]" (page 23, lines 16-18) because the biological function or a specific pathway associated with any deficiency, disease or disorder, has not been yet established for a polypeptide of SEQ ID NO: 32, encoded by SEQ ID NO: 31.

To employ the DNA and the protein in the future methods generation of antibodies or diagnostic assays is not a "real world" because it would eventually relate to a protein for which no biological function is known. The instant application also fails to demonstrate use of the protein as a marker for any disease or condition (which would be a real world use). Because the instant specification does not teach a biological activity of the protein, which supports a practical utility, one would not reasonably believe that the administration of the claimed nucleic aicd would prevent or treat any condition or disease, like "a deficiency in a neuron's IEG responsiveness", as implied by the specification (page 23, second paragraph). To employ a

nucleic acid of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the encoded protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 44-61 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 48, 49 and 54-57 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 48, 49 and 54-56 are directed to isolated nucleic acids that are at least 80% or 85% identical to the sequence of SEQ ID NO: 31 or to nucleic acids that encode proteins which have at least 70% or 85% identity to a protein having SEQ ID NO: 32. Claim 57 depends from claims 54 or 56. The instant specification fails to describe the entire genus of nucleic acids,

which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO: 32. This nucleic acid molecule has a nucleic acid sequence of SEQ ID NO: 31. The subject matter, which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are isolated nucleic acids that are at least 80% or 85% identical to the sequence of SEQ ID NO: 31 or to nucleic acids that encode proteins which have at least 70% or 85% identity to a protein having SEQ ID NO: 32. First, the claims are not limited to an isolated polynucleotide with a specific nucleic acid sequence. The claims only require the polynucleotide to share some degree of structural similarity to the isolated nucleic acid of SEQ ID NO: 31. The specification only describes a polynucleotide having the nucleic acid sequence of SEQ ID NO: 31 and fails to teach or describe any other nucleic acid which lacks the sequence of SEQ ID NO: 31 and encodes a protein that is expressed in response to seizure or ischemia. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled

artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the polynucleotide of SEQ ID NO: 31. The specification does not provide a complete structure of those isolated nucleic acids that are at least 80% or 85% identical to the sequence of SEQ ID NO: 31 or nucleic acids that encode proteins which have at least 70% or 85% identity to a protein having SEQ ID NO: 32. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those isolated nucleic acids that are at least 80% or 85% identical to the sequence of SEQ ID NO: 31 or nucleic acids that encode proteins which have at least 70% or 85% identity to a protein having SEQ ID NO: 32) because the specification teaches only the one embodiment of SEQ ID NO: 31. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 44-46, 51-52 and 58-61 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Adams et al. (WO93/16178 document, 1994). Please note that due to the large volume of WO 93/16178 document, 501 pages, only the first page is provided for reference.

Claims 44-46 and 58-61 are directed to an isolated nucleic acid comprising at least 12 bases in length that hybridizes to nucleic acid sequence of SEQ ID NO: 31. Adams et al. describe an isolated nucleic acid sequence that has at least 12 bases that would hybridize to the instant sequence of SEQ ID NO: 31, see a copy of the printout alignment attached to the instant office action. Because Adams et al. describe isolated human cDNA sequence that anticipates claims 44-46 and 58-61, it also meets the limitations of claims 51-52, which are directed to host cells containing the instant nucleic sequences.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
December 20, 2002 *OC*

JOHN ULM
PRIMARY EXAMINER
GROUP 1800